DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9 44 Hd

November 25, 2003

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2004-DAL-WL- 08

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jack R. Munn, R.Ph., President
Medical Park Pharmacy
9786 Skillman St.
Dallas, Texas 75243

PRODUCTS:
Albendazole
Clenbuterol
Dexamethasone
Enrofloxacin
Ivermectin
Phenylbutazone Powder
Levamisole Hcl
Sulfadiazine Sodium
Cisapride

Dear Mr. Munn:

An inspection of your veterinary drug compounding operation, located at the above address, conducted by an investigator of the Food and Drug Administration (FDA) from this office on July 28/August 6, 2003, disclosed significant violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator was accompanied by Mr. Cy Weich, R.Ph., Chief Compliance Officer of the Texas State Board of Pharmacy (TSBP).

Our investigation has determined that Medical Park Pharmacy is exceeding the regulations under which a compounding pharmacy may compound veterinary drugs. Our findings include, but may not be limited to:

* The use of bulk active pharmaceutical ingredients (APIs) under circumstances that create public health concerns. Your compounded drugs are processed using bulk APIs. When used in food animals, these drugs present particular safety concerns because of the possibility that unsafe drug residues could occur in edible tissues. Your compounded drugs are essentially duplicates of FDA approved animal drug products available on the market. Additionally, some compounded animal drugs, such as cisapride, have been withdrawn from the market for human use for safety reasons .

* Distribution of compounded animal drugs labeled "FOR VETERINARY CLINIC USE," and otherwise lacking directions for patient specific use. The prescription drugs distributed to individuals, farms, ranches, feed stores, veterinarians, and animal clinics by your firm often fail to record critical information necessary to establish treatment for a specific species, or identification of the animal(s) to receive treatment. Prescription drug labeling frequently fails to indicate directions for use, and instead indicates "See Veterinary References for Dosage for Species and Organism." Drugs compounded for food animals do not bear a withdrawal time established by a State licensed veterinarian; instead withdrawal times printed on your product labels are provided by your firm, and are not backed by scientific data supporting the withdrawal periods indicated.

The veterinary drugs compounded and distributed by your firm are new animal drugs within the meaning of section 201(v) of the Act (21 U.S.C. § 321(v)). These animal drugs are adulterated under section 501(a)(5) of the Act (21 U.S.C. § 351(a)(5)) because they are unsafe within the meaning of section 512 of the Act (21 U.S.C. § 360b). Section 512, in part, deems a new animal drug to be unsafe unless an approved New Animal Drug Application (NADA) is in effect for the specific product in question. None of the animal drugs you compound and distribute are the subject of an approval by FDA.

The only legal compounding of animal drugs is provided under the Animal Medicinal Drug Use Clarification Act and its implementing regulations at 21 CFR Part 530, Extralabel Drug Use in Animals. 21 CFR § 530.13 allows a veterinarian or pharmacist to compound animal drugs on the lawful written order of a licensed veterinarian only if certain conditions are met. The conditions include the requirement that the compounding be within the context of a valid veterinarian-client-patient relationship (VCPR), and that the compounding be conducted only with the use of approved drug products. However, your firm compounded animal drugs using bulk APIs, which is not permitted under 21 CFR § 530.13(a). Moreover, some of your animal drugs were compounded using the bulk drug substance cisapride, which was withdrawn from the market for safety reasons. In addition, it appears that your products were being compounded outside the context of a valid VCPR, as required by 21 CFR § 530.10(a), and that your products were not labeled with directions for use specified by a veterinarian, including the animal or animals in which the drug is intended to be used, as required by 21 CFR § 530.12(c).

The above is not intended to be an all-inclusive list of violations by your firm. It is your responsibility to ensure that your firm's operations and products are in compliance with the law and applicable regulations. Our inspectional findings were listed on a Form FDA 483, Inspectional Observations, which was issued and discussed with you at the end of the inspection.

You should take prompt action to correct the noted violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory sanctions. These sanctions include, but are not limited to, seizure and/or injunction.

Within fifteen (15) working days of receiving this letter, you should notify this office in writing of the specific steps you have taken to correct the violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time period within which the corrections will be completed. You may address your reply to James R. Lahar, Compliance Officer, at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

cc: [redacted]